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Pesticide Fact Sheet Number 152: Malathion

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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

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Office of Pesticide Programs (TS-766C)
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EPA

Pesticide Fact Sheet

Name of Chemical: MALATHION
Reason for Issuance: REGISTRATION STANDARD
Date Issued: JAN - 1 1988
Fact Sheet Number: 152

1. DESCRIPTION OF CHEMICAL

Generic Name (Chemical): O,O-dimethyl phosphorodithioate of diethyl mercaptosuccinate

Common Name: Malathion

Trade and Other Names: S-1,2-bis(ethoxycarbonyl)ethyl O,O-dimethyl phosphorodithioate; diethyl(dimethoxyphosphinothioyl)thiobutanedioate; diethyl mercaptosuccinate S-ester with O,O-dimethyl phosphorodithioate; O,O-dimethyl dithiophosphate of diethyl mercaptosuccinate; [S-(1,2-dicarbethoxyethyl) O,O-dimethyl phosphorodithioate; diethyl mercaptosuccinic acid, S-ester with O,O-dimethyl phosphorodithioate; American Cyanamid Co. (USP 2578 652) Code No. EI4049; Calmathion; Celethion; Cythion (deodorized grade); Chemathion; Malaspray; Detmol MA 96% (Albert & Co., Germany); Emmatos; Emmatos Extra; For-Mal (Forshaw Chemicals); Fyfanon; Hilthion; Karbofos; Kop-Thion; Kypfos; Malamar; Malaphele; Malathion ULV Concentrate; Malatol; Maltox (All-India Medical); Prentox Malathion 95% Spray; Sumitox; Vegfru Malatox; Zithiol; Malmed.

EPA Pesticide Chemical Code (Shaughnessy Number): 057701

Chemical Abstract Service (CAS) Number: 121-75-5

Year of Initial Registration: 1956

Pesticide Type: Insecticide and Miticide

Chemical Family: Organophosphate

U.S. and Foreign Producers: American Cyanamid Company, A/S Cheminova, McLaughlin Gormley King Company, Prentiss Drug and Chemical Corp., Inc., Carmel Chemical Corp., Amvac Chemical Corp., Prochimie International Inc., Gowan Co., Wesley Industries Inc., Trans Chemic Industries Inc., Southern Mill Creek Products Co., Inc., Octagon Process Inc., FMC Corp., and Aceto Chemical Co. Inc.

2. USE PATTERNS AND FORMULATIONS

Application Sites: Terrestrial food crop use on alfalfa, almond, anise, apple, apricot, asparagus, avocado, barley, beets, beets (seed crop), bermudagrass, blackberry, blueberry, boysenberry, broccoli, brussels sprouts, cabbage, cantaloupe, carrot, casaba melons, cauliflower, celery, cherry, chestnut, citrus fruits (nursery stock), clover, collards, corn cotton, cowpeas (hay), crenshaw melons, cucumber, currant, dandelion, date, dewberry, eggplant, endive, fig, filbert, flax, garlic, gooseberry, grapefruit, grapes, grass, grass hay, green beans, guava, honeydew melons, honey ball melons, horseradish, kale, kidney beans, kohlrabi, kumquat, leek, lemon, lespedeza, lettuce, lima beans, lime, loganberry, lupine, macadamia nut, mango, muskmelons, mustard greens, navy beans, nectarine, oats, okra, onion, onion (green), onion (seed crop), papaya, parsley, parsnip, passion fruit, pasture grasses, peach, peanuts, pear, peas, pecan, peppermint, peppers, persian melons, pineapple, rangeland grasses, raspberry, rutabaga, rye, safflower, salsify, shallot, snap beans, sorgum, soybeans, spearmint, spinach, squash, strawberry, sugar beets, sweet potato, swiss chard, tangelo, tangerine, tomato, turnips, vetch, walnut, watercress, watermelons, wax beans, and wheat;

Terrestrial non-food crop use on tobacco, tobacco (transplant) beds), ornamental flowering plants, ornamental lawns and turf, ornamental nursery stock, ornamental woody plants, pine seed orchards and uncultivated non-agricultural areas;

Greenhouse food crop use on asparagus, beans, beets, celery, cole crops (including broccoli, cabbage, kale mustard greens, and turnips), corn cucumber, eggplant, endive, lettuce, melons, mushrooms, onion, peas, peppers, potato, radish, spinach, squash, summer squash, tomato, and watercress;

Greenhouse non-food crop use on ornamental plants and Epcot display crops;

Aquatic food crop uses on cranberry and rice;

Aquatic non-food uses on intermittently fooded areas, irrigation systems, and sewage systems;

Forestry uses on forest trees (including Douglas fir, eastern pine, hemlock larch, pines, red pine, spruce, and true fir);

Indoor uses on stored commodity treatment for almonds, barley, field corn, field or garden seeds, grapes (raisin), oats, peanuts, rice rye, sorghum, sunflower, wheat, bagged citrus pulp, and cattle feed concentrate blocks (non-medicated); pet and domestic animal uses for beef cattle, cats, chickens, dairy cattle (lactating and non-lactating), dogs, ducks, geese, goats, hogs, horses (including ponies), pigeons, sheep, and turkeys; animal premise uses for dairy and livestock barns, stables and pens, feed rooms, poultry houses, manure piles, garbage cans, garbage dumps, kennels, rabbits on wire, beef cattle feed lots and holding pens, cat sleeping quarters, dog sleeping quarters, poultry houses; agricultural premise uses for cull fruit and vegetable dumps; household uses for indoor domestic dwellings, human clothing (woolens and other fabrics), mattresses; and commercial and industrial uses for bagged flour, cereal processing plants, edible and inedible commercial establishments, dry milk processing plants, edible and inedible eating establishments, edible and inedible food processing plants, packaged cereals, pet foods and feed stuff.

Methods of Application: Sprays, aerosols and fogging equipment, ground and aerial equipment (including ULV), baits, paints, pet collars, dips, soil, bark and foliar application, dormant and delayed dormant application, animal dust bags and oilers, and cattle feed concentrate blocks.

Formulations: Wettable powders, dusts, granules, emulsifiable concentrates, liquids, solids, impregnated materials, and pressurized sprays, pellets/tablets, liquids (ready to use).

3. SCIENCE FINDINGS

Summary Science Statement

Technical malathion is a mildly acutely toxic pesticide, which is placed in Toxicity Category III based on the oral, dermal and inhalation routes of exposure. Technical malathion is non-sensitizing and only mildly irritating to the eyes and skin (Toxicity Category III and IV, respectively). Additional data are required to assess the neurotoxic potential of malathion. Malathion is a cholinesterase inhibitor, reducing plasma and red blood cell cholinesterase.

Although the Agency possesses a number of studies on the chronic effects of malathion and its principal metabolite malaoxon, several of these studies are deficient scientifically, and must repeated.

Of five studies concerning the oncogenicity of malathion and its metabolite, three are acceptable, and demonstrate that malathion is not carcinogenic in two species of rats, and that its metabolite malaoxon is not carcinogenic in mice. Because of questionable liver findings in the malathion mouse study and the malaoxon rat study, new studies must be conducted in these species.

An acceptable rabbit teratology study demonstrated no teratogenicity at dosages up to 100 mg/kg/day. However, developmental and maternal toxicity were noted at dosages of 50 mg/kg/day. A similar study in rats was unacceptable and must be repeated. A 3-generation reproduction study was also unacceptable.

Laboratory data show that technical malathion is potentially highly toxic to aquatic invertebrates, bees, and aquatic life stages of amphibians; moderately toxic to birds, and slightly toxic to fish. Based on theoretical calculations, both terrestrial and aquatic uses of malathion may pose significant risk to aquatic fauna. Reported fish kills and results of field studies suggest that adverse effects to both aquatic and terrestrial fauna may result from normal use of malathion. However, these studies are not adequately documented to enable EPA to propose restrictions on the use of malathion. EPA will reassess the impacts of malathion use on nontarget organisms after the required environmental fate and ecological effects data have been received and reviewed.

The Agency is unable to assess the potential for malathion to contaminate groundwater because the environmenal fate of malathion is largely uncharacterized. Preliminary data indicate that malathion is very mobile in loamy sand and loam soils. Additional data are needed in order for the Agency to assess its fate in the environment and potential for contaminating groundwater.

A tolerance reassessment of malathion is not possible at this time, since most of the tolerances are not adequately supported, and because there are gaps in the chronic toxicology data base (chronic feeding studies, teratology study, reproduction study, mutagenicity studies, and a metabolism study). The Theoretical Maximal Residue Contribution (TMRC) for the U.S. population average is 0.1014 mg/kg/day and the Provisional Acceptable Daily Intake (PADI) is 0.02 mg/kg/day based on a human study in which plasma and red blood cell cholinesterase were monitored and a 10-fold uncertainty factor was used. The TMRC occupies 507% of the PADI.

Chemical/Physical Characteristics of the Technical Material

Chemical/Physical Characteristics (technical grade)	Color: colorless, yellow, amber, or brown Physical state: Liquid Odor: Mercaptan-like Specific gravity: 1.2315 at 25°C Boiling point: 156-157°C at 0.7 mm Hg Solubility: 145 ppm in water at 25°C; completely soluble in most alcohols, esters, high aromatic solvents, and ketones; poor solubility in aliphatic hydrocarbons. Vapor pressure: 0.00004 mm Hg at 30°C Miscibility: miscible with most organic solvents Stability: may gel in contact with iron, terreplate or tinplate

Toxicology Characteristics

Acute Oral: Toxicity Category III (ranges from 1546 to 1945 mg/kg in female rats and 1522 to 1650 mg/kg in male rats).

Acute Dermal: Toxicity Category III (>2000 mg/kg in female and male rats and rabbits).

Acute Inhalation: Toxicity Category III based on toxicity values ranging from 1.7 to >4.0 mg/m^3 in rats.

Primary Dermal Irritation: Toxicity Category IV based on mild dermal irritation reported in a rabbit study

Primary Eye Irritation: Toxicity Category III based on findings of mild conjunctival reactions 72 hours post application in rabbits' eyes.

Skin Sensitization: Non-sensitizing

Delayed Neurotoxicity: Data gap.

Subchronic Inhalation: Data gap.

Oncogenicity: Data gaps for mouse (using malathion) and rat (using malaoxon).

Chronic Feeding: Data gaps for rodent and nonrodent (using malathion) and rodent (using malaoxon).

Metabolism: Data gap.

Teratogenicity: Data gap for rat. Data in rabbit indicated a NOEL = 25 mg/kg for developmental effects; it was not teratogenic in any dose group (Highest Dose Tested was 100 mg/kg).

Reproduction: Data gap.

Mutagenicity: Data gap.

Environmental Characteristics

Data gaps exist for environmental fate. Data reviewed by the Agency indicate that malathion is very mobile in laomy sand and loam soils. Adsorption ratios reported (amount adsorbed/initial concentration) were 0.73 to 0.95. Data are needed before the Agency can assess the potential for malathion to contaminate groundwater.

Ecological Characteristics (technical grade)

Avian oral toxicity (8-day LD_{50})	167 ppm for ring-necked pheasant and 1485 ppm for mallard.
Avian dietary toxicity (8-day LC_{50})	Acute toxicity value of 3497 ppm for bobwhite and >5000 ppm for mallard
Freshwater fish acute toxicity (96-hr LC_{50})	200 ppm for rainbow trout and 40 to 103 ppm for bluegill
Freshwater invertebrate toxicity (48-hr EC_{50})	1 ppm for Daphnia magna
Estuarine invertebrate toxicity	>1000 ppm for Eastern oyster

Tolerance Assessment

The available data pertaining to metabolism of malathion in plants are inadequate. Additional data are required on the uptake, distribution, and metabolism of malathion in alfalfa, cotton, soybeans, and either wheat or rice. The data pertaining to metabolism of malathion in animals are inadequate. Additional metabolism studies are required that utilize ruminants and poultry. Metabolism studies using cattle, poultry, and swine reflecting direct animal treatment are also required.

Analytical methodology for determining the levels of residues of malathion in plants and animals is adequate. Malathion is detected by the FDA-USDA multiresidue protocols.

Storage stability data demonstrate that residues of malathion in or on frozen plant commodities are stable up to 185 days after application and in milk stored at -10°C for 98 days after application. No data are currently available for animal tissues and are required. Additional storage stability data are also required in order to evaluate the adequacy of the malathion tolerances.

Insufficient data are available on the magnitude and levels of residues of malathion in or on all commodities listed in 40 CFR 180.111 except flax seed, hops, wild rice, and non-medicated cattle feed concentrate blocks. Processing studies are required.

Tolerances must be proposed and appropriate supporting residue data submitted for the following feed items: beanvines and hay; lentil forage and hay; cowpea seed; soybean straw; barley forage, hay and straw; corn forage and fodder; oat forage, hay and straw; rice straw; rye forage and straw; straw of wild rice; sorghum fodder; lespedeza forage; lupine forage; cotton forage; mint hay; peanut hulls, hay and vines; and pineapple forage.

Feed additive tolerances are required for residues of malathion in or on dried hops and spent hops. A tolerance for residues of malathion in or on anise must be proposed together with supporting residue data. Data are needed to support the use of malathion in food handling establishments. In addition, data reflecting the use of malathion on stored, unfinished tobacco are required.

Based on a study in humans in which red blood cell and plasma cholinesterase activity were inhibited at a dose of 0.34 mg/kg (the lowest effect level or LEL), a NOEL has been extrapolated to 0.2 mg/kg/day. A provisional acceptable daily intake (PADI) of 0.02 mg/kg/day has been calculated using a 10-fold uncertainty factor. The PADI is provisional because the existing data base on malathion is lacking chronic toxicity studies, an acceptable teratology study in rats, an acceptable reproduction study, mutagenicity studies, and a metabolism study.

The Theoretical Maximal Residue Contribution (TMRC) for the U.S. population average is 0.1014 mg/kg/day, occupying 507% of the PADI. For children 1 to 6 years of age, the TMRC occupies 1133% of the PADI. The TMRC is based upon current tolerance levels and an assumption that 100% of the sites are treated. Actual exposure levels are likely to be much lower. When the required data are submitted, the Agency will conduct a full tolerance reassessment.

4. SUMMARY OF REGULATORY POSITIONS AND RATIONALES

* No referral to Special Review is being made at this time.

* No new tolerances for raw agricultural commodities or significant new uses will be granted until the Agency has received data sufficient to perform a tolerance reassessment. Significant new uses will not be granted until the data gaps have been filled.

* The Agency is concerned about the potential hazards to aquatic organisms. However, no regulatory action is being considered at this time for fish and wildlife concerns. EPA will reassess the impacts of malathion use on nontarget organisms after the required environmental fate and ecological effects data have been received and reviewed.

* The Office of Endangered Species (OES) in the U.S. Fish and Wildlife Service has determined that certain uses of malathion may jeopardize the continued existence of endangered species or critical habitat of certain endangered species. No additional labeling is required at this time; however, EPA is developing a program to reduce or eliminate exposure to these species, and may require labeling revisions when the program is developed.

* In order to meet the statutory standard for continued registration, the Agency has determined that malathion products must bear revised and updated fish and wildlife toxicity warnings.

* The Agency is deferring decisions concerning malathion's potential for contamination of groundwater until the environmental fate data have been submitted and reviewed.

* The Agency is not restricting the use of malathion products for retail sale only to certified applicators. Malathion does not meet any of the criteria of 40 CFR 162.11 and therefore products containing malathion do not warrant restricted use classification.

* The Agency is not establishing a longer reentry interval for agricultural uses of malathion beyond the minimum reentry interval for all agricultural uses of pesticides (sprays have dried, dusts have settled and vapors have dispersed). The Agency will reassess the need for reentry data/reentry intervals upon receipt of the required toxicology data.

5. SUMMARY OF OUTSTANDING DATA REQUIREMENTS

Toxicology	Time Frame
Delayed neurotoxicity	9 mos.
21-day dermal toxicity	9 "
90-day inhalation - rat	15 "
Chronic toxicity (rodent and non-rodent)--using malathion)	50 "
Chronic toxicity (rodent)--using malaoxon	50 "
Oncogenicity (mouse)--using malathion	50 "
Oncogenicity (rat)--using malaoxon	50 "
Teratogenicity - rat	15 "
Reproductive effects - rat (2-generation)	39 "
Mutagenicity	9-12 mos
Metabolism	24 mos
Domestic animal safety testing	15 "
Environmental Fate/Exposure	
Hydrolysis	9 mos
Aerobic and anaerobic soil metabolism	27 "
Aerobic and anaerobic aquatic metabolism	27 "
Leaching and adsorption/desorption	12 "
Terrestrial field dissipation	27 "
Long-term field dissipation	50 "
Forestry dissipation	27 "
Aquatic (sediment) - field study	27 "
Phhotodegradation in water, soil, air	9 "
Volatility (lab)	12 "
Rotational crops (confined)	39 "
Accumulation in irrigated crops	39 "
Accumulation in fish	12 "
Accumulation in aquatic nontarget organisms	12 "
Spray drift	18 "
Residue Chemistry	
Storage stability data	18 mos
Plant and animal metabolism	18 "
Residue data - raw agricultural commodities	18 "
Processing studies	24 "
Residue data on stored, unfinished tobacco	18 "
Residues in water	15 "
Residue data on food handling establishments	12 "

Product Chemistry	Time Frame
All	9-15 mos

Fish and Wildlife

Acute toxicity to freshwater invertebrates	9 mos
Acute toxicity to estuarine and marine organisms	12 "
Avian reproduction	24 "
Fish early life stage	15 "
Aquatic invertebrate life cycle	15 "
Honeybee - toxicity of residues on foliage	15 "

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